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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/555,467	09/11/2006	Cheung Hoi Yu	2055.043	7542
23405 7590 10/14/2011 HESLIN ROTHENBERG FARLEY & MESITI PC 5 COLUMBIA CIRCLE ALBANY, NY 12203			EXAMINER CHUNDURU, SURYAPRABHA	
			ART UNIT 1637	PAPER NUMBER
			MAIL DATE 10/14/2011	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/555,467	YU ET AL.	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1,2,4-19 and 26-41 is/are pending in the application.
- 5a) Of the above claim(s) 1,2,4,17-19 and 26-41 is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 5-16 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 02 November 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-302) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/3/11; 9/19/11</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 01, 2011 has been considered.

Status of the Application

2. The action is in response to the RCE filed on June 01, 2011. Currently claims 5-16 are pending under examination. Claims 3, 20-25 are cancelled. Claim 1-2, 4, 17-19, 26-41 were previously withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group. All arguments were fully considered and thoroughly reviewed and deemed persuasive for the reasons that follow.

Information Disclosure Statement

3. The Information Disclosure Statement filed on January 03, 2011 and September 09, 2011 have been considered.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

A. Claims 5-8, 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Garin et al. (Microbes and Infection, Vol. 3, pp. 739-745, 2001).

Garin et al. teach a method of claim 5, 10, for nucleic acid (RNA) detection comprising the steps of nucleic acid isolation of pathogenic agent, pre-amplification of the pathogen (cDNA synthesis) and performing real time PCR (RTD amplification) on the pre-amplified nucleic acid (cDNA) (see page 740, section 2-1 to 2.5).

With regard to claim 6, Garin et al. teach that the nucleic acid amplification comprises nucleic acid amplification technique (see page 740, section 2.4).

With regard to claim 7, Garin et al. teach that said real time PCR uses fluorescently labeled probe (see page 740, section 2.5).

With regard to claim 8, Garin et al. teach that the nucleic acid detected is cDNA (see page 740, section 2-1 to 2.5).

With regard to claim 11, Garin et al. teach that the method further comprises obtaining RNA from the biological sample and converting the RNA to cDNA using reverse transcriptase (see page 740, section 2-1 to 2.5).

With regard to claim 12, Garin et al. teach that the steps amplification and real time PCR uses primers (see page 740, section 2.5). Accordingly the claims are anticipated.

B. Claims 5-13 are rejected under 35 U.S.C. 102(a) as being anticipated by Poon et al. (Clin Chem., Vol. 49, No. 6, April 18, 2003).

Poon et al. teach a method of claim 5, 10, for nucleic acid (RNA) detection comprising the steps of nucleic acid isolation of pathogenic agent, pre-amplification of the pathogen (cDNA synthesis) and performing real time PCR on the pre-amplified nucleic acid (cDNA) (see page 953, col.2, paragraph 1).

With regard to claim 6, Poon et al. teach that the nucleic acid amplification comprises nucleic acid amplification technique (cDNA synthesis) (see page 953, col.2, paragraph 1).

With regard to claim 8-9, 13, Poon et al. teach that the nucleic acid detected is SARS cDNA (see page 953, col.2, paragraph 1).

With regard to claim 11, Poon et al. teach that the method further comprises obtaining RNA from the biological sample and converting the RNA to cDNA using reverse transcriptase (see page 953, col.2, paragraph 1).

With regard to claim 12, Poon et al. teach that the steps amplification and real time PCR uses primers (see page 953, col.2, paragraph 1). Accordingly the claims are anticipated.

C. Claims 5-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Ren et al. (US 7,527,926).

Ren et al. teach a method of claim 5, 10, for nucleic acid (DNA) detection comprising the steps of nucleic acid isolation of pathogenic agent, pre-amplification of the pathogen (PCR) and performing real time PCR on the pre-amplified nucleic acid (see col. 27, line 59-67, col. 28, line 56-67, col. 29, line 1-67, col. 30, line 1-67, col. 31, line 1-67, col. 32, line 1-19, Fig.3, col. 36, line 28-67).

With regard to claim 6, Ren et al. teach that the nucleic acid amplification comprises PCR, NASBA or other amplification techniques (see col. 30, line 1-41).

With regard to claim 8-9, 13, Ren et al. teach that the nucleic acid detected is DNA and cDNA of SARS (see page col. 30, line 1-67).

With regard to claim 11, Ren et al. teach that the method further comprises obtaining RNA from the biological sample and converting the RNA to cDNA using reverse transcriptase (see col. 43, line 60-67, col. 44, line 1-67).

With regard to claim 7, 12, Ren et al. teach that the steps amplification and real time PCR uses primers and probe (see col. 30, line 54-67, col. 31, line 1-67, col. 36, line 1-67).

With regard to claims 14-16, Ren et al. teach primers and probes for amplification and detection of SARS that includes SEQ ID No.1 and primers do not overlap with the probe (see Fig. 1 of the Ren et al. disclosure). Accordingly the claims are anticipated.

Response to Arguments:

5. With regard to the rejection of claims 5-16 under 35 USC 103(a) as being obvious over Peiris et al. in view of Therianos et al., the Applicants' arguments were fully considered and the rejection is withdrawn herein in view of the persuasive arguments.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Suryaprabha Chunduru/

Primary Examiner, Art Unit 1637